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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,780	07/05/2001	Gary W. Wood	70012590-04	5013

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EXAMINER
HARRIS, ALANA M

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 07/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/899,780	WOOD, GARY W.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-17 and 23-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-17 and 23-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments and Amendment

1. Claims 13-17 and 23-30 are pending.

Claim 13 has been amended.

Claims 29 and 30 have been added.

Claims 13-17 and 23-30 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Grounds of Rejection

Claim Rejections - 35 USC § 103

3. The rejection of claims 13-17, 23, 24, 28 and newly added claims 29 and 30 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,766,920 (issued June 16, 1998/ IDS reference), further in view of U.S. Patent number 5,290,551 (issued March 1, 1994/ IDS Reference) is maintained and made.

Applicants argue that the amendment to claim 13 to recite that the vaccine is comprised of GM-CSF is neither taught nor suggested by the cited prior art. Applicant asserts in Remarks submitted March 11, 2004 that the "'920 [p]atent only uses GM-CSF as a nonspecific autologous lymphocyte activator of the cultured cells, not as an adjuvant for the vaccine." Applicant further asserts that "the claimed invention of the present invention shows unexpected results" and submits a declaration (March 11,

2004) attesting to this assertion. These arguments, points of view and declaration have been carefully considered, but found unpersuasive.

Patent '920 does state in column 3, lines 6-11 that the "immunoreactive cells of the invention ...require further exposure to an immune stimulant, such as...a cytokine....". And column 5, lines 47-54 sets forth that GM-CSF was contained in a mixture of nonspecific autologous lymphocyte activators and OKT3. Intrinsically, this GM-CSF would act as an immunological adjuvant. It is art known that an innate property of GM-CSF is to augment a humoral and/or cellular response against cancer. Moreover, the declaration and information therein submitted by Applicant is not commensurate in scope. The results presented in the declaration provide data regarding astrocytoma and renal cell carcinoma, but Applicant is reminded that independent claim 13 is a broad claim and does not specify any particular malignancy. It is noted that dependent claims 23 and 24 do limit the malignancy to breast and astrocytoma, respectively. Information provided in the declaration does not aid in obviating the instant rejection. For the reasons of record and set forth herein the rejection is maintained and made.

Applicant's U.S. Patent # 5,766,920 teaches a process of producing and enhancing a population of immunoreactive cells, polyclonal T cells, see column 2, line 11-column 3, line 16. "The process involves removing a patient's mononuclear cells and exposing the cells in vitro to substances which enhance the immune function of the cells", see column 2, lines 15-18. The mononuclear cells may also be derived from tumor or tumor-draining lymph node, see column 2, lines 42-44. The mononuclear cells, such as

peripheral blood mononuclear cells (PBMC) are contacted with OKT3 (art known and the same as anti-CD3) to yield a population of immunoreactive cells, see column 2, lines 23-36, column 3, lines 44-49. The immunoreactive cells are further exposed to an immune stimulant such as an antigen, an inflammatory molecule or a cytokine, such as granulocyte macrophage-colony stimulating factor (GM-CSF) and interleukin-2 (IL-2) in vitro to yield a population of immunoreactive cells, see column 3, lines 6-12 and column 5, lines 2-16; 47-63. The PBMC were obtained from patients by leukopheresis, see column 9, lines 25-27. This method of enhancing and expanding the T cell effector population is effective in the treatment of any type of cancer, including both solid tumors and hematologic tumors, such as breast carcinoma and astrocytomas, see column 7, lines 30-36. Patent '920 does not teach a method of vaccinating a patient with a vaccine comprised of the patient's own malignancy and an immunologic-adjuvant and that the removal of primed peripheral blood T lymphocytes from the patient.

However, U.S. Patent #5,290,551 teaches the intradermal injection of a vaccine consisting of autologous, cyropreserved, irradiated tumor cells mixed with the immunological adjuvant, see column 4, lines 60-63. The patients' peripheral blood T lymphocytes are primed at this stage. It would be *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to implement the teachings of both patents to vaccinate a cancer patient with their own malignancy in order to augment the patient's immune response to treat cancer and establish a primed population of effector T lymphocytes capable of recognizing the malignancy. With this augmentation of the patient's immune system intrinsically primed peripheral blood T

lymphocytes would be a part of the mononuclear population to be removed. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of these references that the endpoint is the effective treatment of cancer. Moreover, the generation of therapeutically relevant numbers T-lymphocytes specifically sensitized with increased specificity for the malignancy would be brought about utilizing the teachings of both patents. And patent '920 sets forth an analogous method in which "[m]ononuclear cells taken from a patient afflicted with a complex chronic viral disease may ...be processed...to yield immunoreactive cells which can then be returned to the patient to augment the patient's immune response to the pathogen", see column 7, lines 40-44.

4. The rejection of claims 13-17, 23-28 and newly added claims 29 and 30 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,766,920 (issued June 16, 1998/ IDS reference), further in view of U.S. Patent number 5,290,551 (issued March 1, 1994/ IDS Reference) is maintained and made.

The teachings of the patents have been established in the preceding paragraphs. Neither patent teaches that the patient is vaccinated at multiple body sites with at least 5×10^6 malignant cells and the patient is vaccinated at the time of initial diagnosis.

However, although the claims recite these specific treatment points in reference to time of diagnosis and dosages of malignant cells, no positive recitation of the methods distinguishes the claims over the references. Therefore, the references read on the treatment at the time of initial diagnosis and at multiple body sites with the

specified amount of malignant cells. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to begin cancer treatment in an expeditious manner in order to impede metastasis, as well as administrating in various sites to effectively eradicate the tumor cells that may have metastasized and to further limit comprising the individual's health. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success since dosages of any composition for treatment must be adjusted and optimized and primed/activated cells reinfused into patients enhances the immune system to treat cancer immediately. Thus the claimed subject matter is considered obvious over the prior art, absent sufficient factual evidence to the contrary.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The examiner works a flexible schedule, however she can normally be reached on 7:00 am to 4:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Y. Chan can be reached on (571)272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
20 May 2004